

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO WAVE 4 CASES ON ATTACHED EXHIBIT A	

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF
DEFENSE EXPERT OLGA RAMM**

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Plaintiffs respectfully request that this Court exclude certain expert testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Olga Ramm, M.D. ("Dr. Ramm"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Olga Ramm is an Obstetrician/Gynecologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge her qualifications as such.¹ Dr. Ramm's general reports set forth opinions on all liability issues with regard to the TVT, including failure to warn and design defect, to include opinions on the material properties of polypropylene mesh. However, Dr. Ramm has no experience drafting warnings or designing mesh devices. Dr. Ramm's experience in the field of Obstetrics and Gynecology does not render all of her opinions admissible. The admission of Dr. Ramm's unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury.² As this Court previously noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'"³ Accordingly, Dr. Ramm should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

¹ Wave 4 TVT General Expert Report of Olga Ramm, M.D. at p. 1 (attached as Ex. B); *see also* Curriculum Vitae of Dr. Ramm (attached as Ex. C).

² *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'") (citing *Daubert*, 509 U.S. at 596).

³ *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.⁴ The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge.⁵

ARGUMENT

I. Dr. Ramm's General Opinions on Warnings Should Be Precluded or Limited

Dr. Ramm is unqualified to offer opinions on the adequacy of the Ethicon TVT Warnings to include the Instructions for Use ("IFU"). First, Dr. Ramm has never drafted an IFU.⁶ Nor, has she provided input to a medical device company on what information needs to be included in an IFU.⁷ Second, Dr. Ramm offers her opinion on the adequacy of Ethicon's warnings but admitted that she only definitively reviewed the 2015 and 2011 TVT IFUs.⁸ Yet, Dr. Ramm offers the opinion that all of Ethicon's TVT IFUs are adequate without ever having reviewed them. Any opinion Dr. Ramm has on all versions of the TVT IFUs outside of the 2015 and 2011 IFUs is pure speculation, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent.⁹ Not only does Dr. Ramm possess inadequate experience, training, and knowledge with regard to drafting IFUs, she only relied on

⁴ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

⁵ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

⁶ See Ramm 3/17/2017 Dep. at 59:3-7 (attached as Ex. D).

⁷ *Id.*

⁸ *Id.* at 45:2-17; 58:24-59:2.

⁹ *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); see also *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

the 2015 and 2011 IFUs in formulating her opinions. Therefore, Dr. Ramm's opinions on the adequacy of Ethicon's TVT warnings are unreliable and should be precluded. At a minimum, Dr. Ramm's opinions on any TVT IFU outside of the 2015 and 2011 versions should be precluded.

II. Dr. Ramm's General Opinions on the Design and Material Properties of the TVT Should Be Precluded or Limited.

Dr. Ramm does not have any experience in materials engineering and has never designed mesh devices; however, she arbitrarily offers opinions regarding the design and the material properties of Ethicon's TVT device.¹⁰ Specifically, she opines that polypropylene is inert, does not undergo mechanical changes or degrade, and that the material properties of polypropylene do not have any clinical significance for patients.¹¹ Dr. Ramm simply does not have the requisite experience to proffer this opinion. Dr. Ramm's opinions amount to nothing more than assumptions, and therefore are unreliable under *Daubert*.¹²

Dr. Ramm is a board certified Obstetrician/Gynecologist with a practice focused on female urology and pelvic floor medicine.¹³ Dr. Ramm does not have any specialized education, training, or applicable relevant experience specifically related to the design or material properties of polypropylene mesh devices.¹⁴ In fact, Dr. Ramm concedes that she has never designed mesh devices nor has she designed any type of polymer.¹⁵ She has never even examined explanted mesh under an electron microscope.¹⁶ Furthermore, she has never provided input to mesh

¹⁰ See Ex. B; Ramm 3/17/2017 Dep. at 72:13-15, 84:1-4.

¹¹ See Ex. B.

¹² *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); see also *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

¹³ See Ex. B at 1; Ex. C.

¹⁴ *Id.*

¹⁵ See Ramm 3/17/2017 Dep. at 72:13-15, 83:15-18.

¹⁶ *Id.* at 69:23-70:2.

manufacturers on the optimal porosity or weight of a mesh device.¹⁷ Specifically, she has never provided an opinion as to how any sling device should be designed.¹⁸ Despite her lack of education, experience, and training about the design and material properties of polypropylene mesh devices, Dr. Ramm attempts to opine on TVT's design and material properties, including degradation, inertness, weight, porosity, and cut (laser or mechanical).¹⁹ These opinions undoubtedly exceed the bounds of her qualifications and should be precluded under *Daubert*.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from Olga Ramm, regarding (a) the adequacy of the TVT warnings and (b) opinions regarding the design and scientific properties of the TVT mesh device. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com
Attorneys for Plaintiffs

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¹⁷ *Id.* at 84:9-23.

¹⁸ *Id.*

¹⁹ *See* Ex. B; Ex. C.

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 13, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com